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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,621	10/06/2006	Maria Elena Ferrero	2503-1228	3886

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EXAMINER
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ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,621	FERRERO, MARIA ELENA	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 16, 2006 (Prelim. Amdt)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *August 16, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

The instant Abstract is not is US format and is too brief to be adequately informative. In particular the abbreviation "o-ATP" needs to be defined with a complete chemical name or preferably a chemical structure.

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure.

No claims have been cancelled, claims **1-4** have been amended, the disclosure has **not** been amended, and no new claims have been added as per the preliminary amendments filed August 16, 2006. An Information Disclosure Statement (1 IDS) filed August 16, 2006 has been received with all cited references and made of record.

Claims **1-6** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

Claims **5 and 6** are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki,* 153 USPQ 678 (Bd. App., 1967) and *Clinical Products, Ltd. v. Brenner,* 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

Applicant is respectfully requested to note the term "use" in claims **5 and 6**. Examiner suggests substitution of the term -- administration --.

Claims **1-6** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant disclosure has only provided two examples wherein the effectiveness of "o-ATP" in the inhibition of cell division of one class of endothelial cell is disclosed. This showing, together with the previous assertions of applicant's theory of the scope of the pharmaceutical activity of o-ATP, is insufficient as written description to support claims **1-6** wherein a vast array of combinations of o-ATP with other generic classes of pharmaceuticals has been asserted by applicant to be active against a large number of generic disease conditions, including the generic terms "tumour" and several different cancers, wherein angiogenesis is well known in the art to be a necessary condition to support the growth of the neoplastic tissue. Applicant's assertions are not deemed to be believable because of the absence of direct test evidence showing that the o-ATP in combination with other effective pharmaceuticals have activity against any disease condition in either an intact living host or in an appropriately selected cell culture. See *Ex parte Balzarini et al.* 21, USPQ 2d 1892, 1894 (BPAI, 1991), a decision in its first part standing for the proposition that claims directed to medicinal treatments of diseases in highly unpredictable art areas (cancer and tumour treatments remain highly unpredictable particularly in the area of neoplasms of the nervous system and the pancreas) are properly rejected under 35 U.S.C. §112, first paragraph as lacking adequate enablement, in the absence of sufficient test data in support of the efficacy of the alleged treatment. See the MPEP at §2107.03 for additional guidance concerning this policy.

Claims **1-6** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for the inhibition of cell division of a single cell type by the administration of "oxidized adenosine triphosphate," does not reasonably provide enablement for the treatment of any neoplastic or other disease condition wherein the inhibition of angiogenesis or any other effect caused by administration of o-ATP is an effective approach. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The instant claims are directed to the treatment of a vast array of generically defined disease conditions wherein angiogenesis is effectively inhibited by administration of an effective amount of oxidized ATP (o-ATP), and to pharmaceutical compositions wherein o-ATP is present in combination with a vast array of other medicinally active substances.

B. The nature of the invention: The invention is directed to treating diseases wherein angiogenesis is a necessary part of disease progression and therefore, according to the theory of the disclosure, the inhibition of angiogenesis by o-ATP would be effective in treating the disease.

C. The state of the prior art: Following a review of the art of record it is clear that "o-ATP" (defined as the dialdehyde produced by periodate oxidation of ATP) is capable of interfering with certain purinergic receptors, but there is no disclosure in said prior art of the administration of o-ATP alone or in combination with other medicinally active substances to treat neoplastic diseases, atherosclerosis, or any other disease condition wherein angiogenesis is an essential part of disease development and/or disease progression over time.

D. The level of one of ordinary skill: The ordinary practitioner in the instant art area would be expected to have experience in medical practice and an understanding of biological sciences.

E. The level of predictability in the art: Predictability is inversely proportional to the knowledge of the ordinary practitioner concerning the treatment of the entire spectrum of the disease conditions claimed herein to be effectively treated. Neither the instant disclosure nor the prior art provide any guidance concerning how to practice the instant claimed method of treatment, thereby rendering the instant art area highly unpredictable.

F. The amount of direction provided by the applicant: The instant disclosure provides only two examples wherein the effect of o-ATP is disclosed as being effective in the inhibition of the cell growth of only one a cell line: human umbilical venous endothelial cells (HUVEC). No additional data is presently of record to support the extrapolation of this data to the instant claimed subject matter wherein o-ATP is administered in combination with a vast array of different classes of medicinally active ingredients to treat a vast array of disease conditions including "ocular diseases," "atherosclerosis," and "tumours" listed in claim **3** and at least 7 different specific neoplastic diseases listed in claim **4**.

G. The existence of working examples: Only two working examples have been provided as described in the preceding paragraph.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because of the absence of sufficient test data and associated guidances. The absence of sufficient test data means that the ordinary practitioner does not have the guidances necessary to practice the vast array of different disease treatments without undue experimentation.

The disclosure is objected to because of the following informalities:

At page 3, line 4, the phrase "It is therefore object of the present invention the use of o-ATP ..." is grammatically incomplete. Did applicant intend the term to read -- It is therefore the object of the present disclosure ~~invention~~ to illustrate the use of o-ATP ... --. Applicant is respectfully requested to edit the remainder of the disclosure to insure that all other grammatical errors are also effectively addressed.

The instant disclosure is incomplete because it does not contain a "Brief Description of the Figures."

Appropriate correction is required.

Claims **1, 2 and 4-6** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim **1** is incomplete because no disease condition to be treated has been explicitly named. Claim **2** has the same problem.

In claim **1** the term "o-ATP" renders the instant claim incomplete because the meaning of the abbreviation has not been provide in the claim. Examiner suggests that the term should be amended to read -- oxidized ATP (o-ATP) --. In view of the chemical formula of "o-ATP" found at page 11, column 1 of the **Granstein et al. '612** reference (PTO-1449 ref. **1**), examiner also notes that the name "oxidized ATP" is misleading because **Granstein's** o-ATP has been both oxidized and reduced, suggesting that the complete chemical structure should also be displayed as part of claim **1** to insure that the intended meaning of the active ingredient in the claimed method of treatment has been accurately represented. Amendment of the disclosure in a similar fashion is also suggested and would not be found to be new matter. Examiner also notes that "o-ATP" is defined as the 2',3'-dialdehyde produced by periodate oxidation of ATP by applicant in the **Ferrero '737** reference (PTO-1449 ref. **5**), an indication that the abbreviation "o-ATP" does not have an agreed upon meaning in the art.

In claim **4** at lines 2-3, the list of diseases is presumed to be intended to be in the alternative: i.e. applicant is assumed to not be claiming the simultaneous treatment of all 7 neoplastic disease conditions simultaneously. If this is the case, examiner suggests that the term -- or -- needs to be inserted between the last two diseases listed in parallel with the format provided as part of the more generic listing in claim **3**.

Claims **5 and 6** appear to be two attempts to claim two different "pharmaceutical composition[s]." The standard format for this type of claim is as follows: -- A pharmaceutical composition comprising {active ingredient(s)} in combination with a pharmaceutically acceptable carrier.-- The above noted claims are incomplete because they have not specified a carrier. Examiner also notes that the term "contains" implies a narrow claim scope (e.g. like -- consisting --), a situation wherein another inventor may incorporate the instant claimed subject matter into another claim with additional limitations and instant applicant will not be able to

assert any property rights. Substitution of the term -- comprising -- corrects this problem and, in the event of issuance, would grant broad coverage and permit assertion of property rights over all claims asserting the granted subject matter as a component part in a more complex composition.

Claims **1-4** would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. §112 set forth in this Office action.

Claims **5 and 6** would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. §112 and §101 set forth in this Office action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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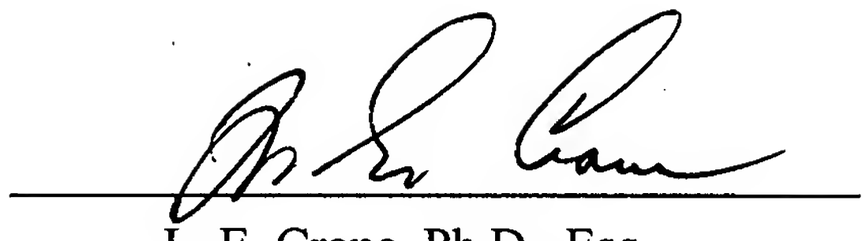
04/26/2007



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